

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/800,031
Applicant : Tara Lynn BIELSKI, et al.
Filed : March 15, 2004
TC/A.U. : 4173
Examiner : Tristan J. Mahyera
Docket No. : 1592-473
Customer No. : 06449
Confirmation No. : 6868

Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION under 37 C.F.R. §1.131

We, Tara Lynn Bielski and Kerry Roy Benson, declare as follows:

1. We are the same Tara Lynn Bielski and Kerry Roy Benson named as inventor on the above-referenced U.S. patent application.
2. Attached hereto as Exhibit 1 is a copy of Master Formula pages for Formula No.: 3422-S05-5, and Exhibit 2 is a copy of Manufacturing Directions pages for Formula No.: 3422-S05-5. The Master Formula pages and the Manufacturing Directions pages were used to produce Batch No: R1K1068 of Formula No.: 3422-S05-5.
3. The originals of these two documents including the handwritten entries were prepared and/or approved prior to August 25, 2003. The photocopies attached hereto are true and accurate copies of the original pages, with the exception that the actual dates of the entries on the Master Formula pages and the Manufacturing Directions pages, and other dates referenced on the pages, have been redacted in the copies provided. After these Master Formula pages and the Manufacturing Directions pages were prepared and

approved, the handwritten entries that appear on these documents were made, signed and dated contemporaneously with the work described therein.

4. The Master Formula pages describe the composition of the formulation containing nitrofurantoin monohydrate and macrocrystals, which falls within the scope of claims of the present application, and the Manufacturing Directions pages describe how to produce this formulation.

5. Specifically, Exhibit 1 consists of 8 pages¹ from the Master Formula, which were prepared under the direction and control of Tara Lynn Bielski and approved by a co-inventor, Kerry Roy Benson. The first page of Exhibit 1 shows information on nitrofurantoin monohydrate/macrocrystals capsules. Each of these capsules contains two tablets comprising 75 mg of nitrofurantoin monohydrate and one tablet comprising 25 mg of nitrofurantoin macrocrystal. Pages 2-5 show that the formulation of nitrofurantoin monohydrate comprises 40.125 mg/unit of nitrofurantoin monohydrate, 40.125 mg/unit of hydroxypropyl methylcellulose, 40.0 mg/unit of sodium alginate and 40.0 mg/unit of alginic acid. The formulation information on pages 3-4 corresponds to Example 1 of the present application. Pages 7-8 show that the formulation of nitrofurantoin macrocrystal comprises 25.0 mg/unit of nitrofurantoin macrocrystals. This formulation information corresponds to Example 2 of the present application.

6. Exhibit 2 consists of 45 pages from the Manufacturing Directions, which were prepared under the direction and control of Tara Lynn Bielski and approved by a co-inventor, Kerry Roy Benson. Pages 9-29 show the instructions on producing tablets containing nitrofurantoin monohydrate formulation which also comprises hydroxypropyl methylcellulose, sodium alginate and alginic acid. The instructions describe granulation/drying (pages 8-18), milling (pages 19-21), blending (pages 22-24) and compression (pages 25-29) procedures. Pages 30-53 describe the instructions for producing tablets containing nitrofurantoin macrocrystals, which consist of instructions

¹ While the Master Formula and the Manufacturing Directions show page numbers in a box appearing the upper right corner of each page, Exhibits 1 and 2 also include pages without such page numbers. Thus, the page numbers indicated in this Declaration are those counting both unnumbered signature pages and the numbered Master Formula and Manufacturing Direction pages.

on blending (pages 30-32), milling (pages 33-34), final blending (pages 35-37) and compression (pages 38-42) procedures. Pages 43-53 show the instructions for encapsulation of the two types of tablets for producing nitrofurantoin monohydrate/macrocrystals capsules. While these instructions are in far more detail because they were used for scale-up testing than what was described in the present application, they clearly evidence that the method for producing the formulation claimed in the present application were completed prior to August 23, 2003.

7. I further declare the all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

Tara Lynn Bielski

Tara Lynn Bielski

06-09-08

Date

Kerry Roy Benson

Date

EXHIBIT 1

MASTER FORMULA

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: 21K1062	PAGE 1
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

FORMULATION INFORMATION

Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422) will contain three tablets as listed below:

- Each of the 100 mg capsules will contain two (2) Nitrofurantoin Monohydrate tablets with a formula weight of 200 mg/tablet or 400 mg total weight. These two tablets are equivalent to 75 mg of Nitrofurantoin Monohydrate.
- Each of the 100 mg capsules will contain one (1) Nitrofurantoin Macrocrystal tablet with a formula weight of 200 mg/tablet. This tablet is equivalent to 25 mg of Nitrofurantoin Macrocrystals.
- The total formula weight of each Nitrofurantoin Monohydrate/Macrocrystals Capsule, 100 mg is 600 mg/capsule.
- This Master Batch Record will be written to allow for processing of each tablet formulation up to the compression stage. Each tablet formula will then be combined during the Encapsulation process to allow for completion of the dosage form.

MASTER PREPARED BY: <i>Eva Beckman</i>	DATE:	MASTER APPROVED BY: <i>Kang Ba</i>	DATE:
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MASTER FORMULA

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422) (Formulation II)		BATCH NO.: <u>R1K1068</u>	PAGE: <u>2</u>
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

mg per unit	Item No.	Ingredient Description	Batch Quantity	Control No.	Scale No.	Wgh'd By	Ck'd By	Date
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NITROFURANTOIN MONOHYDRATE FORMULATION

Note: This formulation represents Nitrofurantoin Monohydrate tablets having a formula weight of 400 mg/tablet. This quantity will be provided for, in the final dosage form, by placing two (2) Nitrofurantoin Monohydrate tablets (with a formula weight of 200 mg/tablet) into each capsule. A theoretical quantity of 360,000 tablets will be produced using this formulation.

WEIGHING INSTRUCTIONS

PART I - GRANULATION SOLUTION

(300.0)	7-448	Purified Water, USP	(59.4 kg)	<u>CD3352A</u>	<u>1160</u>	<u>TP</u>	<u>M. J. J. J.</u>
0		Total Theoretical Weight Part I	0				

NOTE: The Purified Water, USP quantity listed, has ten percent (10%) additional indicated to ensure an adequate amount is available for the granulation process. A total of 54.0 kg (27.0 kg/part) of (Part I) Purified Water, USP is used for the granulation process. The Purified Water, USP does not contribute to the total weight; therefore, its quantity is expressed parenthetically.

Additional Purified Water, USP may be added to the granulation, if necessary, during the granulation process. If additional Purified Water, USP is added, the additional quantity will be weighed in the Granulation Area and the quantity added will be recorded on the Granulation Instructions page.

MASTER PREPARED BY:

DATE:

MASTER APPROVED BY:

DATE:

Edward Nelson

Kerry B.

MASTER FORMULA

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)

BATCH NO.: R1K1068

PAGE 3

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH SIZE: 180,000 Capsules

mg per unit	Item No.	Ingredient Description	Batch Quantity	Control No.	Scale No.	Wgh'd By	Ch'd By	Date
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NITROFURANTOIN MONOHYDRATE FORMULATION

WEIGHING INSTRUCTIONS - Continued

PART II

40.125*	7-731	Nitrofurantoin Monohydrate	7.22 kg	22119	1169	Chen	Wong	
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Active Raw Material Supplier Information: FTS/5.S.T. Corp. (Fill in manufacturer's name)

40.125	7-705	Hydroxypropyl Methycellulose, 2208 (Methocel K100MP)	7.22 kg	28231	1169	A. Holt	N. Wang	
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40.0	7-596	Sodium Alginate (Manucol LKX)	7.20 kg	24312	1169	A. Holt	N. Wang	
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40.0	7-873	Kelacid (Alginic Acid)	7.20 kg	11281	1169	Chen	Wong	
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17.75	7-225	Microcrystalline Cellulose (Avicel PH 102)	3.20 kg	28308	1168	Chen	Wong	
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* Is equivalent to 37.5 mg of Nitrofurantoin.

MASTER PREPARED BY: Anne Hedemont

DATE:

MASTER APPROVED BY: Henry Bao

DATE:

MASTER FORMULA

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: R1K1068	PAGE 4
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

WEIGHING INSTRUCTIONS - Continued

PART III

40.125*	7-731	Nitrofurantoin Monohydrate	7.22 kg	2C119	1169	C. Williams	4/10/68
Active Raw Material Supplier Information: FIS/S.S.T. Corp. (Fill in manufacturer's name)							
40.125	7-705	Hydroxypropyl Methycellulose, 2208 (Methocel K100MP)	7.22 kg	2B231	1169	A. Williams	11/10/68
40.0	7-596	Sodium Alginate (Manucol LKX)	7.20 kg	2A310	1169	A. Williams	11/10/68
40.0	7-873	Kelacid (Alginic Acid)	7.20 kg	11281	1168	C. Williams	4/10/68
17.75	7-225	Microcrystalline Cellulose (Avicel PH 102)	3.20 kg	2B308	1168	A. Williams	4/10/68
178.0		Theoretical Weight Part III	32.0 kg				

* Is equivalent to 37.5 mg of Nitrofurantoin.

MASTER PREPARED BY: <i>Russel Johnson</i>	DATE:	MASTER APPROVED BY: <i>Henry Bon</i>	DATE:
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Q. on 2 March (p. 2)

MASTER FORMULA

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)

BATCH NO.: 21K1068

PAGE 5

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.:

3422-S05-05

BATCH SIZE:

180,000 Capsules

mg per unit	Item No.	Ingredient Description	Batch Quantity	Control No.	Scale No.	Wgh'd By	Ck'd By	Date
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NITROFURANTOIN MONOHYDRATE FORMULATION

WEIGHING INSTRUCTIONS - Continued

PART IV

40.0	7-888	Dibasic Calcium Phosphate, Anhydrous (A-TAB)	7.20 kg	218120	1169	For	2/24/17	
4.00	7-175	Magnesium Stearate	720 grams	240117	1167	A. Holt	11/1/17	
44.0		Total Theoretical Weight Part IV	7.92 kg					
400.0		Total Theoretical Weight of Nitrofurantoin Monohydrate Formulation	72.0 kg					

MASTER PREPARED BY:

Ambermary

DATE:

MASTER APPROVED BY:

Kary B...

DATE:

J

MASTER FORMULA

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)

BATCH NO.: R1K1068

PAGE 6.

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH SIZE:

180,000 Capsules

mg per unit	Item No.	Ingredient Description	Batch Quantity	Control No.	Scale No.	Wgh'd By	CK'd By	Date
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NITROFURANTOIN MACROCRYSTAL FORMULATION

Note: This formulation represents Nitrofurantoin Macrocrystal tablets having a formula weight of 200 mg/tablet. This quantity will be provided for in the final dosage, by placing one (1) Nitrofurantoin Macrocrystal tablet with a formula weight of 200 mg/tablet into each capsule. A theoretical quantity of 180,000 tablets will be produced using this formulation. A

WEIGHING INSTRUCTIONS - Continued

PART V

25.0	7-681	Nitrofurantoin Macrocrystals	4.50 kg	1169	1169	1169	1169	1169
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Active Raw Material Supplier Information: P15/S.S.T. CORP

(Fill in manufacturer's name)

86.2	7-570	Microcrystalline Cellulose (Avicel PH 200)	15.5 kg	1425	1425	1425	1425	1425
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86.0	7-160	Lactose (Fast Flo)	15.5 kg	213068	1425	1425	1425	1425
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0.80	11-278	FD&C Yellow #6 Lake HT (15-18%)	144 grams	1169	1169	1169	1169	1169
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198.0		Total Theoretical Weight Part V	35.6 kg					
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MASTER PREPARED BY: Samuel Newman

DATE:

MASTER APPROVED BY: Samuel Newman

DATE:

MASTER FORMULA

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)

BATCH NO.: 21K1068

PAGE 7.

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.:

3422-S05-05

BATCH SIZE:

180,000 Capsules

mg per unit	Item No.	Ingredient Description	Batch Quantity	Control No.	Scale No.	Wgh'd By	Ck'd By	Date
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NITROFURANTOIN MACROCRYSTAL FORMULATION

WEIGHING INSTRUCTIONS - Continued

PART VI

2.00	7-319	Magnesium Stearate/Sodium Lauryl Sulfate (94/6) (Stear-O-Wet M)	360 grams	11/130	1163	2.116	Blumen	
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2.00		Total Theoretical Weight Part VI	360 grams					
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200.0		Total Theoretical Weight of Nitrofurantoin Macrocrystal Formulation	36.0 kg					
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600.0		Total Theoretical Weight of Capsule Formulation	108.0 kg					
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Released From Weighing By: (QC)

Date: 1/1

MASTER PREPARED BY:

DATE:

MASTER APPROVED BY:

DATE:

Quatechman

Henry Bow

EXHIBIT 2

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.:
3422-S05-05

BATCH NO.:
21K1068

BATCH SIZE:
180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

PART II GRANULATING/DRYING INSTRUCTIONS

Note: The "Fluid Bed Granulating/Drying Processing Parameters" sheet should be referred to for any values requested during the processing steps.

1. On the FL-Multi-60 Fluid Bed Granulator/Dryer Control Panel, access the manual setup display screen and enter the product name and batch number.

Fluid Bed No.: 473

Insert No.: 1220

Performed By: MBPungler

Date:

Checked By: JP

Date:

2. After selecting the "Solvent Solution" to be used, select the Granulator/Dryer option and arm the Fike explosion protection system, (if applicable).

Performed By: MBPungler

Date:

Checked By: JP

Date:

3. Select the manual process function key to access the manual process overview screen.

Performed By: MBPungler

Date:

Checked By: JP

Date:

4. Verify that the proper filter bags are installed in the FL-Multi-60 Fluid Bed unit and verify that the filter seals have been inflated.

Performed By: MBPungler

Date:

Checked By: JP

Date:

5. Equip the above FL-Multi-60 Fluid Bed Granulator/Dryer for processing with a top spray gun assembly using the nozzle size required as per the "Fluid Bed Granulating/Drying Processing Parameters" sheet.

Nozzle Tip Size Verified By: MBPungler

Date:

Checked By: JP

Date:

Performed By: MBPungler

Date:

Checked By: JP

Date:

MASTER PREPARED BY: Russ Hechman

DATE:

MASTER APPROVED BY: Young Bo

DATE:

MBP

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: R1K1062

BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

PART II GRANULATING/DRYING INSTRUCTIONS - Continued

6. Add the (Part II) 3.20 kg Macrocrystalline Cellulose (Avicel PH 102) to the above FL-Multi-60 Fluid Bed Granulator/Dryer product container.
Performed By: MSpungler Date: Checked By: VF Date:
7. Add the (Part II) 7.22 kg Nitrofurantoin Monohydrate to the same product container.
Performed By: MSpungler Date: Checked By: VF Date:
8. Add the (Part II) 7.20 kg Sodium Alginate (Manuocol LKX) to the same product container.
Performed By: MSpungler Date: Checked By: VF Date:
9. Add the (Part II) 7.22 kg Hydroxypropyl Methylcellulose, 2208 (Methocel K100MP) to the same product container.
Performed By: MSpungler Date: Checked By: VF Date:
10. Add the (Part II) 7.20 kg Kelacid (Alginate Acid) to the same product container.
Performed By: MSpungler Date: Checked By: VF Date:
11. Place the product container in position and seal the machine.
Performed By: MSpungler Date: Checked By: VF Date:
12. Access the manual process overview screen, adjust the inlet air temperature setpoint to 45°C (35°C - 55°C), set the shaker interval and duration, solution flow rate, and the atomizing air to the value specified on the "Fluid Bed Granulating/Drying Parameters" sheet.
Notes: 1. During the granulating, drying and cooling processes, adjust the air flow, solution flow rate and shaker interval to the values specified on the "Fluid Bed Granulating/Drying Processing Parameters" sheet at the specified times.
2. Record all processing parameters on the "Fluid Bed Granulating/Drying Processing Sheet."
Performed By: MSpungler Date: Checked By: VF Date:

MASTER PREPARED BY: Rene Heilmann

DATE:

MASTER APPROVED BY: Rene Heilmann

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment,
as required by "Mylan's Standard Operating
Procedures," must be worn when working with
this product.

FORMULA NO.:
3422-S05-05

BATCH NO.:
R1K1062

BATCH SIZE:
180,000 Capsules

PAGE
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NITROFURANTOIN MONOHYDRATE FORMULATION

PART II GRANULATING/DRYING INSTRUCTIONS - Continued

13. Turn on the exhaust fan and adjust the air flow to the specified value.
Performed By: MSpungler Date: _____
Checked By: VP Date: _____
14. Mix for three (3) minutes. Record mixing time below.
Time Start: 7:45 (~~AM~~/PM)
Time Stop: 7:48 (~~AM~~/PM) ✓
Total Time: 3 minutes
Performed By: MSpungler Date: _____
Checked By: VP Date: _____
15. Activate the mechanical shaker.
Performed By: MSpungler Date: _____
Checked By: VP Date: _____
16. Begin spraying and continue until (Part I) 27.0 kg of Purified Water, USP has been added to the batch.
Scale No.: 1282
Performed By: MSpungler Date: _____
Checked By: VP Date: _____
17. Additional Purified Water, USP may be added, if necessary, to obtain an acceptable granulation.
Approval to Add Additional Purified Water, USP By: VP Date: _____

- Record quantity added: N/A kg
- Scale No.: N/A Purified Water, USP Lot No.: N/A
Performed By: MSpungler Date: _____
Checked By: VP Date: _____
18. Upon completion of granulating, turn off the atomizing air and increase the inlet air temperature setpoint to 70°C (60°C - 80°C) and begin drying.
Performed By: MSpungler Date: _____
Checked By: VP Date: _____
- Note: Continue drying until the target endpoint temperature is reached.

MASTER PREPARED BY: Quas Technum

DATE: _____

MASTER APPROVED BY: Randy Ba

DATE: _____

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MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: 21K1008
PAGE 11

BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

GRANULATING/DRYING INSTRUCTIONS - Continued

19. Upon completion of drying adjust the air flow to the specified value and cool until the product temperature endpoint is obtained.

Performed BY: MS Date: Checked BY: VP Date:

20. Upon completion of cooling, turn off the exhaust fan and activate the mechanical shaker.

Performed BY: MS Date: Checked BY: VP Date:

21. Discharge the (Part II) dried granulation into a tared, labeled drum containing two poly-liners.

Performed BY: MS Date: Checked BY: VP Date:

22. Weigh the (Part II) dried Nitrofurantoin Monohydrate granulation:

Container No: 1041 kg kg kg

Gross Weight: 34.6 kg kg kg

Tare Weight: 4.1 kg kg kg

Net Weight: 30.5 kg kg kg

Record the total net weight of the (Part II) dried Nitrofurantoin Monohydrate granulation:

(Tolerances: 30.5 kg kg kg)
(Tolerances: 29.8 kg - 34.3 kg)
(Tolerances: 93.0% - 107.0%)

Scale No.: 1160 Weighed By: MS Date:

Checked By: VP Date:

MASTER PREPARED BY: MS

DATE:

MASTER APPROVED BY: VP

DATE:

Part II gran logs
Checked by: M. J. J. J.

J. P. J. J.

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Microcrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: P1K1068
BATCH SIZE: 180,000 Capsules
PAGE 12

NITROFURANTOIN MONOHYDRATE FORMULATION GRANULATING/DRYING INSTRUCTIONS

Note: The "Fluid Bed Granulating/Drying Processing Parameters" sheet should be referred to for any values requested during the processing steps.

1. On the FL-Multi-60 Fluid Bed Granulator/Dryer Control Panel, access the manual setup display screen and enter the product name and batch number.

Fluid Bed No.: 473

Insert No.: 1226

Performed By: WJungster Date: Checked By: TF Date:

2. After selecting the "Solvent Solution" to be used, select the Granulator/Dryer option and arm the Fike explosion protection system, (if applicable).

Performed By: WJungster Date: Checked By: TF Date:

3. Select the manual process function key to access the manual process overview screen.

Performed By: WJungster Date: Checked By: TF Date:

4. Verify that the proper filter bags are installed in the FL-Multi-60 Fluid Bed unit and verify that the filter seals have been inflated.

Performed By: WJungster Date: Checked By: TF Date:

5. Equip the above FL-Multi-60 Fluid Bed Granulator/Dryer for processing with a top spray gun assembly using the nozzle size required as per the "Fluid Bed Granulating/Drying Processing Parameters" sheet.

Nozzle Tip Size Verified By: WJungster Date:

Performed By: WJungster Date: Checked By: TF Date:

MASTER PREPARED BY: Gene Hearn

DATE:

MASTER APPROVED BY: Ken G. Be

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

BATCH NO.: 21K1068

PAGE 13

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

GRANULATING/DRYING INSTRUCTIONS - Continued

8. Add the (Part III) 3.20 kg Microcrystalline Cellulose (Avicel PH 102) to the above FL-Multi-60 Fluid Bed Granulator/Dryer product container.

Performed By: MP Date: 11/11/11 Checked By: MP Date: 11/11/11

7. Add the (Part III) 7.22 kg Nitrofurantoin Monohydrate to the same product container.

Performed By: MP Date: 11/11/11 Checked By: MP Date: 11/11/11

8. Add the (Part III) 7.20 kg Sodium Alginate (Manuocol LXX) to the same product container.

Performed By: MP Date: 11/11/11 Checked By: MP Date: 11/11/11

9. Add the (Part III) 7.22 kg Hydroxypropyl Methylcellulose, 2208 (Methocel K100MP) to the same product container.

Performed By: MP Date: 11/11/11 Checked By: MP Date: 11/11/11

10. Add the (Part III) 7.20 kg Kelacid (Alginate Acid) to the same product container.

Performed By: MP Date: 11/11/11 Checked By: MP Date: 11/11/11

11. Place the product container in position and seal the machine.

Performed By: MP Date: 11/11/11 Checked By: MP Date: 11/11/11

12. Access the manual process overview screen, adjust the inlet air temperature setpoint to 45°C (35°C - 55°C), set the shaker interval and duration, solution flow rate, and the atomizing air to the value specified on the "Fluid Bed Granulating/Drying Processing Parameters" sheet.

Notes: 1. During the granulating, drying and cooling processes, adjust the air flow, solution flow rate and shaker interval to the values specified on the "Fluid Bed Granulating/Drying Processing Parameters" sheet at the specified times.

2. Record all processing parameters on the "Fluid Bed Granulating/Drying Processing Sheet."

Performed By: MP Date: 11/11/11 Checked By: MP Date: 11/11/11

MASTER PREPARED BY: Paul Hesterman

DATE: 11/11/11

MASTER APPROVED BY: Kang Ba

DATE: 11/11/11

MSB

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: 21K1068 BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

PART III

GRANULATING/DRYING INSTRUCTIONS - Continued

13. Turn on the exhaust fan and adjust the air flow to the specified value.
Performed By: MP Date: Checked By: TF Date:
14. Mix for three (3) minutes. Record mixing time below.
Time Start: 10:05 (AM/PM) ✓
Time Stop: 10:08 (AM/PM) ✓
Total Time: 3 minutes
Performed By: MP Date: Checked By: TF Date:
15. Activate the mechanical shaker.
Performed By: MP Date: Checked By: TF Date:
16. Begin spraying and continue until (Part I) 27.0 kg of Purified Water, USP has been added to the batch.
Scale No.: 1282
Performed By: MP Date: Checked By: TF Date:
17. Additional Purified Water, USP may be added, if necessary, to obtain an acceptable granulation.
Approval to Add Additional Purified Water: USP By: MP Date:

- Record quantity added: 3.0 kg
- Scale No.: 1282 Purified Water, USP Lot No.: C032502A
- Performed By: MP Date: Checked By: TF Date:
18. Upon completion of granulating, turn off the atomizing air and increase the inlet air temperature setpoint to 70°C (60°C - 80°C) and begin drying.
Performed By: MP Date: Checked By: TF Date:
- Note: Continue drying until the target endpoint temperature is reached.

MASTER PREPARED BY: QuaHeem and

DATE:

MASTER APPROVED BY: Kang Ba

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: <u>21K1062</u>	PAGE 15
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

GRANULATING/DRYING INSTRUCTIONS - Continued

19. Upon completion of drying adjust the air flow to the specified value and cool until the product temperature endpoint is obtained.

Performed By: MPungler Date: 7/7 Checked By: JP Date: 7/7

20. Upon completion of cooling, turn off the exhaust fan and activate the mechanical shaker.

Performed By: MPungler Date: 7/7 Checked By: JP Date: 7/7

21. Discharge the (Part III) dried granulation into a tared, labeled drum containing two poly-liners.

Performed By: MPungler Date: 7/7 Checked By: JP Date: 7/7

22. Weigh the (Part III) dried Nitrofurantoin Monohydrate granulation:

Container No: 141 kg
 Gross Weight: 36.1 kg
 Tare Weight: 4.1 kg
 Net Weight: 32.0 kg
 Record the total net weight of the (Part III) dried Nitrofurantoin Monohydrate granulation: 32.0 kg
 (Tolerances: 29.8 kg - 34.3 kg)
 (Tolerances: 93.0% - 107.0%)

Scale No.: 1160 Weighed By: MPungler Date: 7/7
 Checked By: JP Date: 7/7

MASTER PREPARED BY: <u>Bruce Hechman</u>	DATE: <u>7/7</u>	MASTER APPROVED BY: <u>Young B.</u>	DATE: <u>7/7</u>
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Part III gran. tags
Checked by:
M. J. Munger

J. R. Ristler

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: R1K1D68	PAGE 16
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

MILLING INSTRUCTIONS

- Setup a Fitzmill according to the following parameters:
Fitzmill No.: 24
Screen Size: #18
Blade Position: Knives Forward
Blade Speed: Medium
Fitzmill Parameters Setup By: Fitzmill Date: 11/11/88
Fitzmill Parameters Verified By: M. Spungler Date: 11/11/88
- Pass the (Part II) dried granulation through the above Fitzmill into a tared, labeled drum containing two poly-liners.
Performed By: TR Date: 11/11/88 Checked By: M. Spungler Date: 11/11/88
- Weigh the (Part II) milled material:
Container No.: 1081
Gross Weight: 34.4 kg
Tare Weight: 4.2 kg
Net Weight: 30.4 kg
Record the total net weight of the (Part II) milled material: 30.4 kg
(Tolerances: 29.2 kg - 34.3 kg)
(Tolerances: 91.0% - 107.0%)
Weighed By: Fitzmill Date: 11/11/88
Checked By: M. Spungler Date: 11/11/88
- Pass the (Part III) dried granulation through the above Fitzmill into a tared, labeled drum containing two poly-liners.
Performed By: TF Date: 11/11/88 Checked By: M. Spungler Date: 11/11/88

MASTER PREPARED BY: <u>Fitzmill</u>	DATE:	MASTER APPROVED BY: <u>Paul R.</u>	DATE:
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MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: 21K1068

BATCH SIZE: 180,000 Capsules

PAGE 17

NITROFURANTOIN MONOHYDRATE FORMULATION

MILLING INSTRUCTIONS - Continued

5. Weigh the (Part III) milled material:

Container NO.: 1441 kg kg kg kg kg kg
Gross Weight: 31.9 kg kg kg kg kg kg
Tare Weight: 41.2 kg kg kg kg kg kg
Net Weight: 31.9 kg kg kg kg kg kg

Record the total net weight of the (Part III) milled material: 31.9 kg
(Tolerances: 29.2 kg - 34.3 kg)
(Tolerances: 91.0% - 107.0%)

Scale No.: 1441 Weighed By: J. Partridge Date: 11/1/01

Checked By: MP Date: 11/1/01

6. Record the sum of the Part II and Part III milled material: 62.3 kg
(Tolerances: 58.3 kg - 68.6 kg)
(Tolerances: 91.0% - 107.0%)

Performed By: TP Date: 11/1/01 Checked By: MP Date: 11/1/01

MASTER PREPARED BY: Quach Hedmond

DATE: 11/1/01

MASTER APPROVED BY: Randy Bo

DATE: 11/1/01

Muller's top checked by
M. J. P. M.
P. J. M.

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: PK1062
BATCH SIZE: 180,000 Capsules
PAGE 18

NITROFURANTOIN MONOHYDRATE FORMULATION

BLENDING INSTRUCTIONS

- Screen the (Part IV) 720 grams Magnesium Stearate through a #18 mesh screen into a tared, labeled drum containing two poly-liners.
Screener No.: Shedder
Performed BY: Mpungile Date: Checked BY: TF Date:
- Screen the (Part IV) 7.20 kg Dibasic Calcium Phosphate, Anhydrous (A-TAB) through a #18 mesh screen into a tared, labeled drum containing two poly-liners.
Performed BY: Mpungile Date: Checked BY: TF Date:
- Add the (Part II) milled granulation to a five (5) cubic foot "V" Blender.
Blender No.: 1334
Performed BY: Mpungile Date: Checked BY: VP Date:
- Add the (Part IV) screened Magnesium Stearate to the same "V" Blender.
Performed BY: Mpungile Date: Checked BY: TF Date:
- Add the (Part IV) screened Dibasic Calcium Phosphate, Anhydrous (A-TAB) to the same "V" Blender.
Performed BY: Mpungile Date: Checked BY: TF Date:
- Add the (Part III) milled granulation to the same "V" Blender.
Performed BY: Mpungile Date: Checked BY: TF Date:
- Blend for fifteen (15) minutes. Record blending time below.
Time Start: 12145 (AM/PM)
Time Stop: 1:00 (AM/PM) ✓
Total Time: 15 minutes.
Performed BY: Mpungile Date: Checked BY: TF Date:

MASTER PREPARED BY: Mahekmony

DATE:

MASTER APPROVED BY: Kang Bo

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: 21K1068	PAGE 19
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

BLENDING INSTRUCTIONS - Continued

8. Notify Quality Control for sampling. Discharge the blended material, relative to the sampling requirements for this product. Discharge into tared, labeled drums containing two poly-liners or into a clean, tared Transfer Vessel.

Circle Container Used:

Drums

Vessel

Transfer Vessel Equipment No.: N/A

☒ Sampled prior to discharging.

☒ Sampled after discharging.

(If samples are pulled before and after discharging, check both boxes.)

Sampled by: (OC) Chris P. [Signature]

Date: 11/11/08

[Blend Uniformity Analysis Acceptance Criteria: 90.0% - 110.0% of the Theoretical Drug Content with a Relative Standard Deviation of Not More Than 5.0%.]

Performed By: JP

Date: 11/11/08

Checked By: MB [Signature] Date: 11/11/08

9. Weigh the Nitrofurantoin Monohydrate blended material:

Container No.: 141 kg 141 kg
 Gross Weight: 137 kg 137 kg
 Tare Weight: 47 kg 47 kg
 Net Weight: 69.6 kg 69.6 kg
 Record the total net weight of the Nitrofurantoin Monohydrate blended material:

(Tolerances: 63.4 kg - 77.0 kg)
 (Tolerances: 88.0% - 107.0%)

Scale No.: 141

Weighted By: J. [Signature]

Date: 11/11/08

Checked By: MB [Signature]

Date: 11/11/08

10. Place "Hold for Test" stickers on the containers and transfer to the In-Process Quarantine Area.

Performed By: JP

Date: 11/11/08

Checked By: MB [Signature] Date: 11/11/08

MASTER PREPARED BY: Chris P. [Signature]

DATE: 11/11/08

MASTER APPROVED BY: Paul B. [Signature]

DATE: 11/11/08

Small Blend bag
checked by:
M. Brown
A. H. H. H.

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: PK1068

BATCH SIZE: 180,000 capsules

NITROFURANTOIN MONOHYDRATE FORMULATION

COMPRESSION INSTRUCTIONS

Released to Compression By: (OC) MCN Date: 11/11

1. Weigh the Nitrofurantoin Monohydrate blend received into compression:

Container No.: 141 kg
Gross Weight: 73.7 kg
Tare Weight: 4.1 kg
Net Weight: 69.6 kg

Record the total net weight of the Nitrofurantoin Monohydrate blend received:

(Tolerance: \pm one-half (0.5) kg of the weight from previous department) 69.6 kg
Scale No.: 1159 Weighed By: McQuigley Date: 11/11
Checked By: B. J. Quigley Date: 11/11

2. Verify setup has been performed on a rotary tablet press to include the below listed punches and dies:

Tablet Press Equipment No.: 35

Die Size: 1/4" Round
Upper Punch: 1/4" Round, flat-faced
Lower Punch: 1/4" Round, flat-faced
Mono: None

Verified By: McQuigley Date: 11/11 Checked By: B. J. Quigley Date: 11/11

Theoretical Weight: 200 mg Individual Tablet Weight 200 mg Average Tablet Weight 200 mg
Range: 185 mg - 215 mg
3. Compress a sufficient quantity of Nitrofurantoin Monohydrate tablets to obtain target hardness, thickness and weight.
Performed By: McQuigley Date: 11/11

MASTER PREPARED BY: Paul Heilmann DATE: 11/11 MASTER APPROVED BY: Paul Heilmann DATE: 11/11

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: 21K1068

BATCH SIZE: 180,000 Capsules

PAGE 21

NITROFURANTOIN MONOHYDRATE FORMULATION

COMPRESSION INSTRUCTIONS - Continued

4. Record the weight, hardness and thickness of the Nitrofurantoin Monohydrate tablets on the compression forms.

Record the tablet compression rate being used:

Performed By: MSM/mgk Date: 6/83 1000 rpm

5. When the above tablets fail within the acceptance criteria listed, notify the Quality Control Department to take a sample for Physical Testing.

Performed By: MSM/mgk Date: 6/83

Sampled By: (OC) Date: 6/83

6. Perform the tests listed below and record the results:

1. Thickness: 0.175 - 0.183 Inches
2. Hardness: 9.3 kp
3. Weight Check: Pass
4. Appearance: OK
5. Sample Match: OK
6. Friability: 0.1 %

Recorded By: (OC) Date: 6/83

Approved For Compression By: (OC) Date: 6/83

7. Upon approval, compress the remaining blend into tablets.

NOTE: Operator(s) will sign the compressing forms throughout the run as verification of the compression of the batch.

MASTER PREPARED BY: Quachhehman

DATE:

MASTER APPROVED BY: James Bo

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: 21K1068

BATCH SIZE: 180,000 Capsules

PAGE 22

NITROFURANTOIN MONOHYDRATE FORMULATION COMPRESSION INSTRUCTIONS - Continued

8. Accountability:

Weight of Acceptable Nitrofurantoin Monohydrate Tablets:

Container No.: 1011 8 bars 0.10 kg Waste
Gross Weight: 18.1 kg 90.8 kg
Tare Weight: 18.1 kg 8.0 kg 26.1 kg
Net Weight: kg 64.7 kg kg

Record the total net weight of acceptable Nitrofurantoin Monohydrate tablets:

(Tolerances: 64.7 kg 52.6 kg - 72.0 kg)
(Tolerances: 73.0 g - 100.0 g)

Scale No.: 1157 Weighed By: MP Date:

Checked By: TS Date:

Quantity of Sample Tablets: 1.9 kg ✓

Recorded By: TS Date:

Weight of Waste:

Description: Success Rate PC Waste
Gross Weight: 8.0 kg 1.0 kg
Tare Weight: 0.1 kg 0.1 kg
Net Weight: 1.9 kg 0.9 kg

Record the total net weight of waste: 2.8 kg ✓

Scale No.: 1157 Weighed By: MP Date:

Checked By: TS Date:

MASTER PREPARED BY: Anna Hetherington

DATE:

MASTER APPROVED BY: Henry Bo

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment,
as required by "Mylan's Standard Operating
Procedures," must be worn when working with
this product.

FORMULA NO.:
3422-S05-05

BATCH NO.: P1K1068
BATCH SIZE:
180,000 Capsules

PAGE
23

NITROFURANTOIN MONOHYDRATE FORMULATION

COMPRESSION INSTRUCTIONS - Continued

Total net weight of acceptable tablets, sample tablets and waste: 69.4 kg

Performed By: MBaumgarten Date: _____ Checked By: KB Date: _____

Percent of Material Accounted for: 99.7 %
(Tolerances: 99.0% - 101.0% of material received)

Performed By: MBaumgarten Date: _____ Checked By: KB Date: _____

Average Nitrofurantoin Monohydrate Individual Tablet Weight: 200 mg

Recorded By: KB Date: _____

Tablet Yield: 323.5 M
Percent Yield: 99.9 %
(Tolerances: 262.8 M - 360.0 M)
(Tolerances: 73.0% - 100.0%)

Performed By: MBaumgarten Date: _____ Checked By: KB Date: _____

MASTER PREPARED BY:

DATE:

MASTER APPROVED BY:

DATE:

Pure Weinmann

Pure Weinmann

1/2

Mr. J. B. Conner
Tad Conner
and
Mr. J. B. Conner

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: <u>P1K1068</u>	PAGE <u>24</u>
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MACROCRYSTALS FORMULATION

PART V BLENDING INSTRUCTIONS

- Add the (Part V) 15.5 kg Lactose (Fast Flo) to a five (5) cubic foot "V" Blender.
Blender No.: 1334
Performed BY: Myung Lee Date: _____ Checked BY: BA Date: _____
- Add the (Part V) 4.50 kg Nitrofurantoin Macrocrystals to the same "V" Blender.
Performed BY: Myung Lee Date: _____ Checked BY: BA Date: _____
- Add the (Part V) 144 grams FD&C Yellow #6 Lake HT (15-18%) to the same "V" Blender.
Performed BY: Myung Lee Date: _____ Checked BY: BA Date: _____
- Add the (Part V) 15.5 kg Microcrystalline Cellulose (Avicel PH 200) to the same "V" Blender.
Performed BY: Myung Lee Date: _____ Checked BY: BA Date: _____
- Blend for fifteen (15) minutes. Record blending time below.
Time Start: 9:50 (AM/PM) _____
Time Stop: 10:05 (AM/PM) ✓
Total Time: 15 minutes.
Performed BY: Myung Lee Date: _____ Checked BY: BA Date: _____

MASTER PREPARED BY: <u>Myung Lee</u>	DATE: _____	MASTER APPROVED BY: <u>Young Ba</u>	DATE: <u>1</u>
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MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: 21K1008
BATCH SIZE: 180,000 Capsules

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NITROFURANTOIN MACROCRYSTALS FORMULATION

PART V BLENDING INSTRUCTIONS - Continued

6. Discharge the (Part V) blended material into a tared, labeled drum containing two poly-liners.

Performed BY: M. J. [Signature] Date: 7/1/77 Checked BY: BSB Date: 7/1/77

7. Weigh the (Part V) Nitrofurantoin Macrocrystal blended material:

Container No.: 1001 kg
Gross Weight: 39.7 kg
Tare Weight: 4.2 kg
Net Weight: 35.5 kg

Record the total net weight of the (Part V) Nitrofurantoin Macrocrystal blended material:

(Tolerances: 35.5 kg - 36.0 kg)
(Tolerances: 34.9 kg - 101.0%)

Scale No.: 1441 Weighed By: M. J. [Signature] Date: 7/1/77

Checked By: BSB Date: 7/1/77

MASTER PREPARED BY: [Signature]

DATE: 7/1/77

MASTER APPROVED BY: [Signature]

DATE: 7/1/77

Checked
Top Blending
for
B. J. J. J.
W. J. J. J.

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals		BATCH NO.:	PAGE 26
Capsules, 100 mg (3422)		FORMULA NO.:	
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		3422-S05-05	BATCH SIZE:
			180,000 Capsules

NITROFURANTOIN MACROCRYSTALS FORMULATION

PART V MILLING INSTRUCTIONS

1. Setup a Comil according to the following parameters:

Comil No.: 762
 Screen Size: 032 R
 Impeller: Round
 Speed: 700 RPM

Comil Parameters Setup By: MSpungler Date: 1-
 Comil Parameters Verified By: MSpungler Date: 1-

2. Pass the (Part V) Nitrofurantoin Macrocrystal blend through the above Comil into a tared, labeled drum containing two poly-liners.

Performed By: MSpungler Date: 1- Checked By: MSpungler Date: 1-
 Weigh the (Part V) milled Nitrofurantoin Macrocrystal blend:

Container No.: 1061
 Gross Weight: 39.6 kg
 Tare Weight: 4.2 kg
 Net Weight: 35.4 kg

Record the total net weight of the (Part V) milled Nitrofurantoin Macrocrystal blend:

(Tolerances: 35.4 kg - 36.0 kg)
 (Tolerances: 34.2 kg - 101.0 g)

Scale No.: 1441 Weighed By: MSpungler Date: 1-
 Checked By: MSpungler Date: 1-

MASTER PREPARED BY:	DATE:	MASTER APPROVED BY:	DATE:
<u>MSpungler</u>		<u>MSpungler</u>	

Mullins, Miss
 Mullins, Mrs.
 Charles
 Sep. 1891

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment,
as required by "Mylan's Standard Operating
Procedures," must be worn when working with
this product.

FORMULA NO.:
3422-S05-05

BATCH NO.:
21K1068

BATCH SIZE:
180,000 Capsules

NITROFURANTOIN MACROCRYSTALS FORMULATION

FINAL BLENDING INSTRUCTIONS

1. Pass the (Part VI) 360 grams Magnesium Stearate/Sodium Lauryl Sulfate
(94/6) (Stear-O-Wet M) through a #30 mesh screen into a tared, labeled
drum containing two poly-liners.

Screener No.: Blend Screen

Performed By: BSA Date: 1-1-77 Checked By: MPungler Date: 1-1-77

2. Add the (Part V) milled Nitrofurantoin Macrocrystal material to a five (5)
cubic foot "V" Blender.

Blender No.: 1334

Performed By: BSA Date: 1-1-77 Checked By: MPungler Date: 1-1-77

3. Add the (Part VI) screened Magnesium Stearate/Sodium Lauryl Sulfate (94/6)
(Stear-O-Wet M) to the same "V" Blender.

Performed By: BSA Date: 1-1-77 Checked By: MPungler Date: 1-1-77

4. Blend for fifteen (15) minutes. Record blending time below.

10:20

Time Start: 11:20 (AM/PM) AM ✓
Time Stop: 10:35 (AM/PM) PM ✓
Total Time: 15 minutes

Performed By: MPungler Date: 1-1-77 Checked By: BSA Date: 1-1-77

MASTER PREPARED BY: Qua Heilmann

DATE: 1-1-77

MASTER APPROVED BY: Kerry B.

DATE: 1-1-77

NA

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.:
3422-S05-05

BATCH NO.:
R1K10028

BATCH SIZE:
180,000 Capsules

NITROFURANTOIN MACROCRYSTALS FORMULATION

FINAL BLENDING INSTRUCTIONS - Continued

- Notify Quality Control for sampling. Discharge the blended material, relative to the sampling requirements for this product. Discharge into tared, labeled drums containing two poly-liners or into a clean, tared Transfer Vessel.

Circle Container Used:

Transfer Vessel Equipment No.: R14

Drums

Vessel

- ☒ Sampled prior to discharging.
☒ Sampled after discharging.

(If samples are pulled before and after discharging, check both boxes.)

Sampled by: (OC) [Signature]

Date:

[Blend Uniformity Analysis Acceptance Criteria: 90.0% - 110.0% of the Theoretical Drug Content with a Relative Standard Deviation of Not More than 5.0%.]

- Performed BY: M. [Signature] Date: Checked BY: B. [Signature] Date:
Record the weight of the Nitrofurantoin Macrocrystal final blended material.

Container NO.: 1441
Gross Weight: 39.2 kg
Tare Weight: 4.2 kg
Net Weight: 35.0 kg
Record the total net weight of the Nitrofurantoin Macrocrystal final blended material:
35.0 kg
(Tolerances: 33.5 kg - 36.4 kg)
(Tolerances: 93.0% - 101.0%)

Scale No.: 1441 Weighed BY: M. [Signature] Date:
Checked BY: B. [Signature] Date:

- Place "Hold for Test" stickers on the containers and transfer to the In-Process Quarantine Area.

Performed BY: M. [Signature] Date: 3/20/02 Checked BY: B. [Signature] Date:

MASTER PREPARED BY: [Signature]

DATE:

MASTER APPROVED BY: [Signature]

DATE:

108

Amel Blend book
Amel boy
October 1948
W. J. Dunnington
P. J. Dunnington

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.:

3422-S05-05

BATCH NO.:

P1K1068

BATCH SIZE:

180,000 Capsules

NITROFURANTOIN MACROCRYSTALS FORMULATION

COMPRESSION INSTRUCTIONS

Released to Compression By: (cc) M. S. Edwards Date: 11/15/79

1. Weigh the Nitrofurantoin Macrocrystal blend received into compression:

Container NO.: 1061 kg
Gross Weight: 39.3 kg
Tare Weight: 4.2 kg
Net Weight: 35.1 kg

Record the total net weight of the Nitrofurantoin Macrocrystal blend received:

(Tolerance: \pm one-half (0.5) kg of the weight from previous department)

Scale No.: 1159 Weighed By: M. S. Edwards Date: 11/15/79

Checked By: J. H. Harty Date: 11/15/79

2. Verify setup has been performed on a rotary tablet press to include the below listed punches and dies:

Tablet Press Equipment No.: 35

Die Size: 1/4" Round

Upper Punch: 1/4" Round, Flat-Faced

Lower Punch: 1/4" Round, Flat-Faced

Verified By: M. S. Edwards Date: 11/15/79 Checked By: J. P. Date: 11/15/79

Theoretical Weight: 200 mg Average Tablet Weight: 200 mg

Range: 185 mg - 215 mg 190 mg - 210 mg

3. Compress a sufficient quantity of Nitrofurantoin Macrocrystal tablets to obtain target hardness, thickness and weight.

Performed By: M. S. Edwards Date: 11/15/79

MASTER PREPARED BY: M. S. Edwards

DATE: 11/15/79

MASTER APPROVED BY: J. H. Harty

DATE: 11/15/79

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.:
3422-S05-05

BATCH NO.:
21K1068

BATCH SIZE:
180,000 Capsules

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NITROFURANTOIN MACROCRYSTALS FORMULATION

COMPRESSION INSTRUCTIONS - Continued

4. Record the weight, hardness and thickness of the tablets on the compression forms.

Record the tablet compression rate being used to compress the batch:

Performed By: McQuinn Date: 6/83 EDM/rpm

5. When the above tablets fall within the acceptance criteria listed, notify the Quality Control Department to take a sample for Physical Testing.

Performed By: McQuinn Date: 6/83
Sampled By: (OC) Date: 6/83

6. Perform the tests listed below and record the results:

1. Disintegration 5-6 min.
2. Thickness: 0.174-0.184 inches
3. Hardness: 10.1-11.8 kp
4. Weight Check: pass
5. Appearance: OK
6. Sample Match: OK
7. Friability: 0.2 %

Recorded By: (OC) Date: 6/83

Approved For Compression By: (OC) Date: 6/83

7. Upon approval, compress the remaining blend into tablets.

NOTE: Operator(s) will sign the compressing forms throughout the run as verification of the compression of the batch.

MASTER PREPARED BY: Quinn

DATE:

MASTER APPROVED BY: Quinn

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: 21K1068
BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MACROCRYSTALS FORMULATION COMPRESSION INSTRUCTIONS - Continued

8. Accountability:

Weight of Acceptable Nitrofurantoin Macrocrystal Tablets:

Container No.: 10188 kg 40.1 kg 54.2 kg
Gross Weight: 20.1 kg 4.0 kg 24.1 kg
Tare Weight: 20.1 kg 4.0 kg 24.1 kg
Net Weight: 20.1 kg 30.1 kg 30.1 kg

Record the total net weight of acceptable Nitrofurantoin Macrocrystal tablets:

(Tolerances: 30.1 kg - 28.1 kg - 36.0 kg)
(Tolerances: 78.0% - 100.0%)

Scale No.: 1159 Weighed By: M. J. [Signature] Date:

Checked By: [Signature] Date:

Quantity of Sample Tablets: 2.1 kg

Recorded By: [Signature] Date:

Weight of Waste:

Description: Sucra 1.0 kg 0.1 kg 0.1 kg
Gross Weight: 2.0 kg 0.1 kg 0.1 kg
Tare Weight: 0.1 kg 0.1 kg 0.1 kg
Net Weight: 1.9 kg 0.0 kg 0.0 kg

Record the total net weight of waste: 2.8 kg

Scale No.: 1159 Weighed By: M. J. [Signature] Date:

Checked By: [Signature] Date:

MASTER PREPARED BY: [Signature]

DATE:

MASTER APPROVED BY: [Signature]

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.:
3422-S05-05

BATCH NO.:
21K1068

BATCH SIZE:
180,000 Capsules

NITROFURANTOIN MACROCRYSTALS FORMULATION

COMPRESSION INSTRUCTIONS - Continued

Total net weight of acceptable tablets, sample tablets and waste: 35.0 kg

Performed By: MSG Date: Checked By: KB Date:

Percent of Material Accounted for: 99.7 %
(Tolerances: 99.0% - 101.0% of material received)

Performed By: MSG Date: Checked By: KB Date:

Average Individual Nitrofurantoin Macrocrystal Tablet Weight: 200 mg

Recorded By: MSG Date:

Tablet Yield: 150.5 M
Percent Yield: 83.4 %
(Tolerances: 140.4 M - 180.0 M)
(Tolerances: 78.0% - 100.0%)

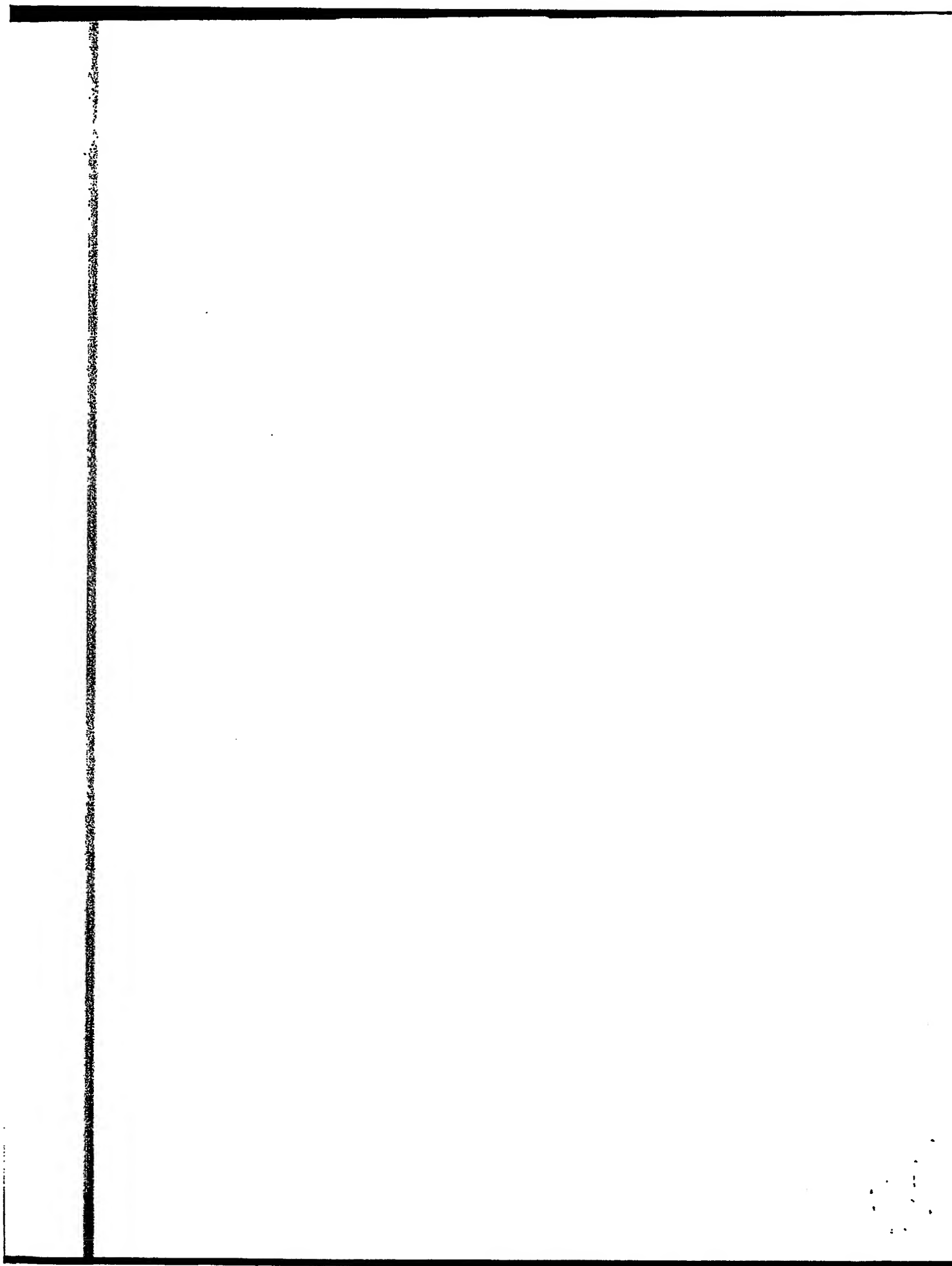
Performed By: MSG Date: Checked By: KB Date:

MASTER PREPARED BY:

DATE:

MASTER APPROVED BY:

DATE:



MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.:
3422-S05-05

BATCH NO.:
21K1068

BATCH SIZE:
180,000 Capsules

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NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS

Released to Encapsulation By: (QC) 102202020

Date: 10/22/02

Weigh the Nitrofurantoin Monohydrate tablets received into encapsulation:

Container No.: 3112 30445 1412121
Gross Weight: 18.1 kg 8.0 kg 21.1 kg
Tare Weight: 0.0 kg 0.0 kg 0.0 kg
Net Weight: 18.1 kg 8.0 kg 21.1 kg

Record the total net weight of the Nitrofurantoin Monohydrate tablets into encapsulation:

(Tolerances: \pm one-half (0.5) kg of the weight from previous Department)

Scale No.: 1155 Weighed By: CHM Date: 10/22/02

Checked By: CHM Date: 10/22/02

Weigh the Nitrofurantoin Macrocrystal tablets received into encapsulation:

Container No.: 48112 100121
Gross Weight: 4.0 kg 34.2 kg 4.0 kg
Tare Weight: 0.0 kg 0.0 kg 0.0 kg
Net Weight: 4.0 kg 34.2 kg 4.0 kg

Record the total net weight of the Nitrofurantoin Macrocrystal tablets into encapsulation:

(Tolerances: \pm one-half (0.5) kg of the weight from previous Department)

Scale No.: 1158 Weighed By: CHM Date: 10/22/02

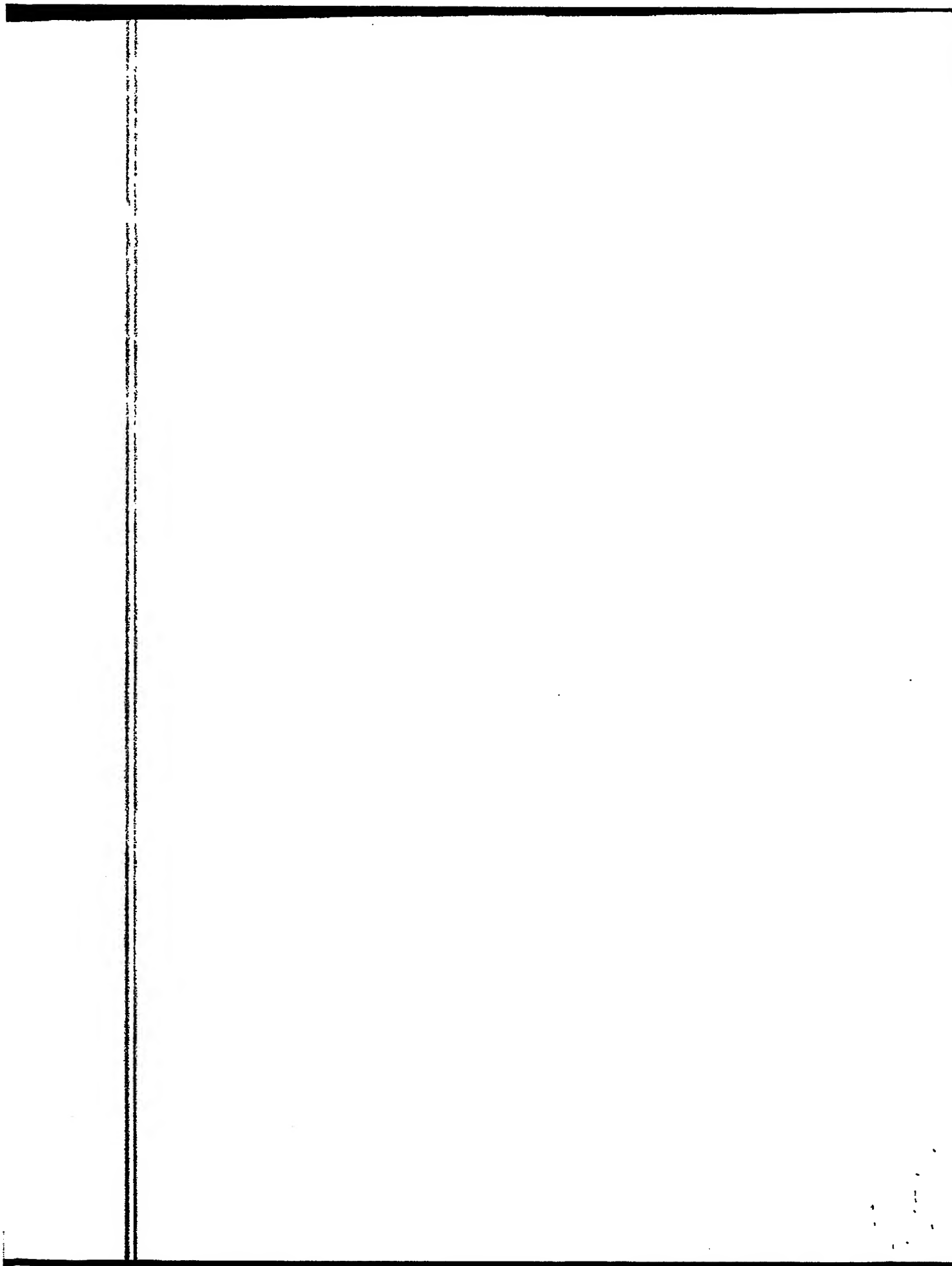
Checked By: CHM Date: 10/22/02

MASTER PREPARED BY: CHM

DATE: 10/22/02

MASTER APPROVED BY: CHM

DATE: 10/22/02



MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: 21K1068

BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS - Continued

Determine the theoretical number of capsules to be encapsulated with Nitrofurantoin Monohydrate tablets.

Note: Two (2) individual tablets will be placed inside each capsule to create the Monohydrate portion of the dosage form.

Record the Average Individual Nitrofurantoin Monohydrate Tablet Weight:

Recorded By: M. Springsteen Date: 10/10/00 (from page 23) ✓

Kilograms of the Monohydrate tablets received =

Average Individual Tablet Weight (mg) (1) 65.0 kg x 1,000,000 = 325,000 tablets ✓ (round as whole number)

325,000 tablets = 162,500 capsules ✓ (round as whole number)

162,500 capsules = 162.5 M capsules (2) * (round to nearest tenth)

Record on page 35.

Performed By: M. Springsteen Date: 10/10/00 Checked By: Paul H. Thompson

MASTER PREPARED BY: Paul H. Thompson

DATE:

MASTER APPROVED BY: Paul H. Thompson

DATE:

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: 21K1068	PAGE 35
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS - Continued

Determine the theoretical number of capsules to be encapsulated with Nitrofurantoin Macrocrystal tablets.

Note: One (1) individual tablet will be placed inside each capsule to create the dosage form.

Record the Average Individual Nitrofurantoin Macrocrystal Tablet Weight:

200 mg⁽³⁾ ✓
 (From page 32)

Recorded By: MB Springsteen Date: _____

Kilograms of the Macrocrystal tablets received = _____
 Average Individual Tablet Weight (mg)⁽³⁾

30.2 kg x 1,000,000 = 151,000 tablets ✓
 200 mg (round as whole number)

151,000 tablets = 151,000 capsules ✓
 1 tablet/capsule (round as whole number)

151,000 capsules = 151.0 M capsules ⁽⁴⁾* ✓
 1000 (round to nearest tenth)

Record below.

Performed By: MB Springsteen Date: _____ Checked By: Carol Williams Date: _____

Record the "Nitrofurantoin Monohydrate theoretical capsule quantity ⁽²⁾" calculated on page 34, below. Record the "Nitrofurantoin Macrocrystal theoretical capsule quantity ⁽⁴⁾" calculated above.

Nitrofurantoin Monohydrate theoretical capsule quantity: ⁽²⁾ 162.5 M ✓

Nitrofurantoin Macrocrystal theoretical capsule quantity: ⁽⁴⁾ 151.0 M ✓

Compare the two recorded quantities above and use the smallest to determine the capsule yield tolerances listed on page 40.

Recorded By: MB Springsteen Date: _____

MASTER PREPARED BY: <u>Carol Williams</u>	DATE:	MASTER APPROVED BY: <u>Carol Williams</u>	DATE:
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MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: 21K1068	PAGE 36
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 capsules

NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS - Continued

Capsule Shell Description

Capsule Shell Size: #0
 Cap Color: Light Gray Opaque (0945)
 Body Color: Light Brown Opaque (3826)
 Imprinted: (Black Imprint) Mylan 3422

Capsule Deductions (Capsule I.D. No.: 72442)
 (Record the lot number(s) and the amount of the empty capsule shells used to encapsulate the batch in the spaces below.)

Amount Deducted: 1200 Capsule Lot No.: 21202
 Amount Deducted: 1200 Capsule Lot No.: 21202

Performed By: Robert J. Wilson Date: _____ Checked By: Jim Thack Date: _____

Capsule Fill Weight Information: (Verify the weights and ranges listed)

Capsule fill weight for Nitrofurantoin Monohydrate tablets:

Note: Two (2) individual tablets will be placed inside each capsule to create the Monohydrate portion of the dosage form.

Theoretical Weight:	Individual Capsule Fill Weight	Average Capsule Fill Weight
Range:	400 mg	400 mg
	360 mg - 440 mg	380 mg - 420 mg

Verified by: Mark Spangale Date: _____

MASTER PREPARED BY: <u>Russ Hedman</u>	DATE: _____	MASTER APPROVED BY: <u>Kay Bo</u>	DATE: _____
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Charles Page
Jim Beach

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH NO.: PK1068 BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS - Continued

Capsule fill weight for Nitrofurantoin Macrocrystal tablets:

Note: One (1) individual tablet will be placed inside each capsule to create the Macrocrystal portion of the dosage form.

Theoretical Weight:	200 mg	Average Capsule Fill Weight
Range:	180 mg - 220 mg	200 mg

Verified by: McMurry Date: 7/1/77

Capsule fill weight for Nitrofurantoin Monohydrate/Macrocrystals Capsules:

Note: Two (2) individual Nitrofurantoin Monohydrate tablets and one (1) Nitrofurantoin Macrocrystals tablet will be placed inside each capsule to create the final dosage form.

Theoretical Weight:	600 mg	Average Capsule Fill Weight
Range:	540 mg - 660 mg	600 mg

Verified by: McMurry Date: 7/1/77

Approval To Proceed BY: (OC) [Signature] Date: 7/1/77

1. In the space provided below, check (✓) the type of encapsulation machine to be used and enter the capsule machine number.

CAPSULE MACHINE NO.

- ☒ MG Encapsulation Machine 1071
- ☐ HK Encapsulation Machine _____
- ☐ Index Encapsulation Machine _____

Performed By: [Signature] Date: _____ Checked By: McMurry Date: 7/1/77

MASTER PREPARED BY: <u>[Signature]</u>	DATE: _____	MASTER APPROVED BY: <u>[Signature]</u>	DATE: <u>1</u>
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MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: <u>P1K1068</u>	PAGE 38
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS - Continued

- On the above selected encapsulation machine, run a sufficient amount of capsules to obtain the proper fill weight required. Record the weight on the encapsulation forms.
- Performed By: Theresa J. H. H. H. Date: 11/11/88 Checked By: MS. J. H. H. Date: 11/11/88
- Contact Quality Control to take samples for physical testing.
- Performed By: Theresa J. H. H. H. Date: 11/11/88
- Sampled By: (QC) MS. J. H. H. Date: 11/11/88
- Weight Check: OK
- Appearance: OK
- Sample Match: 1st Batch OK
- Recorded By: (QC) MS. J. H. H. Date: 11/11/88

Approval to Continue Encapsulation By: (QC) MS. J. H. H. Date: 11/11/88

- Upon approval, encapsulate the remaining tablets.

NOTE:

Operator(s) will sign the encapsulation forms throughout this run as verification of the encapsulation of this batch.

- After encapsulation, sort the batch.
- Verified By: David Still Date: 11/11/88
- After sorting, place the filled capsules on an inspection machine where "defective capsules" will be removed.
- Verified By: MS. J. H. H. Date: 11/11/88
- Record the following:
- Individual Filled Capsule Weight: 111.1 mg
- Average Shell Weight: 94 mg
- Recorded By: (QC) David Still Date: 11/11/88

MASTER PREPARED BY: Theresa J. H. H.

DATE: 11/11/88

MASTER APPROVED BY: MS. J. H. H.

DATE: 11/11/88

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)		BATCH NO.: 21K1068	PAGE 39
PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.		FORMULA NO.: 3422-S05-05	BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS - Continued

8. After inspection, record the following information:

Weight of Acceptable Filled Capsules:

Container No.:	5K10	7 Boxes	Weight
Gross Weight:	18.1	kg	174.4
Tare Weight:		kg	25.1
Net Weight:		kg	89.3

Container No.:		kg	
Gross Weight:		kg	
Tare Weight:		kg	
Net Weight:		kg	

Record the total net weight of acceptable filled capsules: 89.3 kg

Weighed By: John Leary Date: _____
 Checked By: David Still Date: _____

Weight of Sorting Waste:

Description:	Sorting	kg	
Gross Weight:	0.9	kg	
Tare Weight:	0.1	kg	
Net Weight:	0.8	kg	

Record the total net weight of sorting waste: 0.8 kg

Weighed By: John Leary Date: _____
 Checked By: David Still Date: _____

Weight of Inspection Waste:

Description:	Inspect	kg	
Gross Weight:	3.6	kg	
Tare Weight:	0.0	kg	
Net Weight:	3.6	kg	

Record the total net weight of inspection waste: 3.6 kg

Weighed By: John Leary Date: _____
 Checked By: David Still Date: _____

MASTER PREPARED BY: David Still

DATE: _____

MASTER APPROVED BY: John Leary

DATE: _____

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals
Capsules, 100 mg (3422)

PRECAUTIONS: Personal Protective Equipment,
as required by "Mylan's Standard Operating
Procedures," must be worn when working with
this product.

FORMULA NO.:
3422-S05-05

BATCH NO.: 21K1062
BATCH SIZE:
180,000 Capsules

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NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS - continued

Quantity of Sample Capsules: 3.4 kg ✓

Recorded By: (OC) Stoller

Date: _____

Record the total net weight of acceptable capsules, sorting waste,
inspection waste, and sample capsules: 108.3 kg ✓

Performed By: M. J. J. J. Date: _____

Checked By: KB

Date: _____

Capsule Yield:

CALCULATE TOLERANCES AS FOLLOWS:

151.000 M x 0.95 = ⁽⁵⁾ 143.5 M ✓
"theoretical number
of capsules"
(from page 35) (round to nearest tenth)

151.000 M x 1.00 = ⁽⁵⁾ 151.0 M ✓
"theoretical number
of capsules"
(from page 35) (round to nearest tenth)

Calculations Performed By: M. J. J. J.

Date: _____

Calculations Approved By: KB

Date: _____

Number of Doses: 144.1 M ✓
Percent: 95.4 %

(Tolerances: ⁽⁵⁾ 143.5 M to ⁽⁵⁾ 151.0 M)
(Tolerances: 95.0% to 100.0% of "theoretical number of capsules"
calculated on page 35)

Performed By: M. J. J. J. Date: _____

Checked By: KB

Date: _____

MASTER PREPARED BY: Qua Heumery

DATE: _____

MASTER APPROVED BY: Qua Heumery

DATE: _____

MANUFACTURING DIRECTIONS

PRODUCT: Nitrofurantoin Monohydrate/Macrocrystals Capsules, 100 mg (3422)

BATCH NO.: 21K1068 PAGE 41

PRECAUTIONS: Personal Protective Equipment, as required by "Mylan's Standard Operating Procedures," must be worn when working with this product.

FORMULA NO.: 3422-S05-05

BATCH SIZE: 180,000 Capsules

NITROFURANTOIN MONOHYDRATE/MACROCRYSTALS CAPSULES FORMULATION

ENCAPSULATION INSTRUCTIONS - Continued

Weight of Encapsulation Waste:

Description: Recycled #1

Gross Weight: 0.8 kg

Tare Weight: 0.0 kg

Net Weight: 0.8 kg

Recycled #2

10.2 kg

1.0 kg

9.2 kg

Total net weight of encapsulation waste: 10.0 kg ✓

Scale No.: 711

Weighed By: Jeff Kopp

Date: 1/10/08

Checked By: David Stull

Date: 1/10/08

Record the total net weight of acceptable capsules, sample capsules, and all wastes: 110.3 kg ✓

Performed By: M. J. J. J. Date: 1/10/08 Checked By: KR Date: 1/10/08

Percent of Material Accounted For: 100.2% (Tolerances: 99.0% - 101.0% of material received from previous department)

Performed By: M. J. J. J. Date: 1/10/08 Checked By: KR Date: 1/10/08

* Calculated according to R+D-SOP-163

KR
1/10/08

MASTER PREPARED BY: Anna Heilmann

DATE: 1/10/08

MASTER APPROVED BY: Jeff Kopp

DATE: 1/10/08